



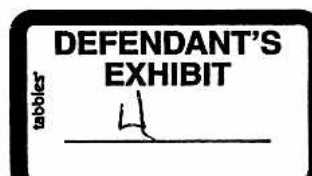
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**TAP Pharmaceuticals Inc.**

**SAMPLE ACCOUNTABILITY  
PROGRAM**

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ACCOUNT # \_\_\_\_\_



TAP 5109639

## **Components of the TAP Procedures Manual**

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Overview and Rep Call Card Kit	Section 1
Reporting Call/Sample Activity	Section 2
Procedures for Ordering Samples	Section 3
Recording Inventory Movement	Section 4

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## **An Overview of This Manual**

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The United States Government has specified a number of requirements controlling the distribution of samples of pharmaceutical products to a physician. These rules can be involved and confusing and a violation can cause serious problems for both a company and an individual Sales Representative.

TAP, with the help of Epsilon, a Boston Company with expertise in sampling, has developed a system to simplify the process. The program has been designed to permit you to deliver samples of products directly to the doctor, to follow all government requirements, and to do it all with a minimum of effort. This manual explains that system and shows you how to order samples, record sample activity, and record inventory activity. In addition a video "Samples are Simple" has been prepared to show you how to correct any problems you may have at the end of the month.

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## **Background**

"The congress finds that the existing system of providing drug samples... has been abused for decades and has resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals."

There were two main problems in the Pharmaceutical Industry:

- Pharmaceutical Sales Representatives were selling products that were to be given to physicians free of charge.
- The samples were being repackaged and sold.

In 1987, the Prescription Drug Marketing Act (PDMA) was made law and placed the following requirements on the distribution of samples:

1. There must be written request and receipt for all samples. It must include:
  - Doctor's Name
  - Doctor's Address
  - Doctor's Professional Designation (MD or DO)
  - Doctor's signature
  - Identification of the product to be sampled
  - Quantity of samples requested
2. All forms must be retained for 3 years
3. All Pharmaceuticals must be stored properly
4. There must be periodic inventory of samples in possession of Sales Representatives
5. Notification of the FDA regarding "significant loss of drug supplies"
6. There must be a system in place to detect potential violations
7. All procedures subject to FDA and Abbott audits

The Act also provided for penalties for non-compliance for BOTH the Sales Representative and the company including fines and imprisonment.

### **Purpose of the Sample System**

To simplify the record keeping for samples as required by the law and to insure that TAP Pharmaceuticals and its Sales Representatives are in compliance with the letter and the spirit of the Prescription Drug Marketing Act.

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**This Manual is divided into three sections**

**Recording Call/Sample Activity** - This section describes eight possible ways to fill out the Sample Signature Card. Each item includes:

- Filling out the Sample Signature Card (in Detail).
- Distributing copies of the Sample Signature Card.
- Avoiding return of the Sample Signature Card.

**Procedures for Ordering Samples** - In this section you will find detailed instructions on how to order samples. You will also find instructions on when and how to return sample goods.

**Recording Inventory Movement** - The process of recording and verifying inventory quantities is covered in this section. The quantities are derived from your receipt of inventory, your monthly physical inventory and your sampling activity. By reviewing monthly reports you can verify that your inventory is in balance with the system's record of your inventory. Adjusting a variance is also discussed in this section.

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Every two (2) months you will receive a "Rep Call Card Kit". The Kit will contain:

#### Rep Call Card Kit

- Physician Master List - a list of every physician in your territory.
- Sample Signature Cards - one or more for each Physician shown on the Physician Master list. These cards are used to report sampling or detailing activity.
- Monthly Physical Inventory Forms - to report all samples on hand at the end of the month.
- Inventory Adjustment Forms - to report corrections to the inventory Epsilon has reported to be in your possession and the reason it is different than expected.
- Business Reply Mail Envelopes - to send in your sample card and other forms to Epsilon.

## Reporting Call/Sample Activity

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This section contains the following:

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TAP 5109645

## Reporting Call/Sample Activity

### Recording Sample/Call Activity with Preprinted Cards

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This section explains how to fill out and submit a preprinted card to report sample/call activity for a physician. It also shows how to avoid having the card returned to you.

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All entries must be in ink (press firmly).

**NOTE:** The use of multiple ink colors within the physician signature box or multiple ink colors in the sample quantity box should be avoided as it may suggest tampering.

Step 1     ✓     Check the box:

☐ Record Sample/Call Activity Only

Step 2     ✎     Fill in the date of the call. Cards without a date will be returned to you.

Step 3     ✓     If you detail the product, check the box:

☐ (✓ if detailed)

Step 4     ✎     Fill in the quantity or boxes of each drug sample you leave with the physician. Place the number on the far right side of the card before the word "QTY".

Step 5     ✎     Write how many of the Lupron Kits given as samples (3.75mg and 7.5mg separately) were for new patient starts and how many were given at your discretion. The total of these two numbers must equal the number shown at the right side of the card by the word "QTY".

Step 6     ✎     In the Notes section, if Lupron samples were left for new patients, list the name of each patient involved.

**NOTE:** White-out or corrections are not acceptable by law. If you make an error, use a new card.

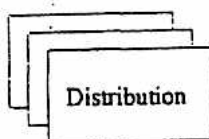
Step 7     ✎     If you leave a sample, the physician must personally sign the card. The physician's signature must match the preprinted name on the card. Other staff can not sign for the physician. Rubber stamps are not acceptable. Unsigned cards will be returned to you.

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<b>TAP PHARMACEUTICALS INC.</b> <b>Sample Signature Card</b> <b>1232840</b>		EPSILON ID: 20145679A		DATE OF CALL: 0124192																																					
<input checked="" type="checkbox"/> RECORD SAMPLE/CALL ACTIVITY ONLY <input type="checkbox"/> ADD (PRE-PRINTED CARD REQUESTED) ENTER INFORMATION ON FRONT OF CARD		<input type="checkbox"/> CHANGE (ENTER CHANGES ON BACK OF CARD) <input type="checkbox"/> NO LONGER IN TERRITORY (MOVED OR DECEASED)																																							
Michael Jones, MD 123 Circle Tree Place New Town, USA 12345		MD DO (CIRCLE ONE)																																							
SPECIALTY: OBG ME # PHONE # 312/445/7658 TERR. # AXA42		TAP ACCT. # 01016573 # CARRIER: 3 EMP. ACCT. #: 00016006																																							
I REQUEST AND ACKNOWLEDGE RECEIPT OF THE # ITEMS INDICATED HEREON FOR THE MEDICAL NEEDS OF MY PATIENTS. I CERTIFY THAT I AM CURRENTLY LICENSED WITH THE APPROPRIATE STATE AUTHORITY TO RECEIVE THESE SAMPLES. X <u>Dr. Michael Jones</u> Physician Signature																																									
<table border="1"> <thead> <tr> <th colspan="2">Lupron Depot</th> <th colspan="2">Ogen</th> </tr> <tr> <th>3.75mg Kit</th> <th>101</th> <th>2</th> <th>QTY</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Discretionary Quantity</td> <td>1.25 6x26 Tube</td> <td>201 1 QTY</td> </tr> <tr> <td>1</td> <td>New Patient Start Quantity</td> <td>1.25 6x26 Tube</td> <td>202 QTY</td> </tr> <tr> <td colspan="2">Notes: Jane Sheehan</td> <td>1 Tube x 14g Cream</td> <td>203 QTY</td> </tr> <tr> <td>7.5mg Kit</td> <td>102</td> <td>QTY</td> <td></td> </tr> <tr> <td colspan="2">Discretionary Quantity</td> <td>Mytrin</td> <td>400 QTY</td> </tr> <tr> <td colspan="2">New Patient Start Quantity</td> <td>Ac21 Tube</td> <td>401 QTY</td> </tr> <tr> <td colspan="2">Notes:</td> <td></td> <td></td> </tr> </tbody> </table>						Lupron Depot		Ogen		3.75mg Kit	101	2	QTY	1	Discretionary Quantity	1.25 6x26 Tube	201 1 QTY	1	New Patient Start Quantity	1.25 6x26 Tube	202 QTY	Notes: Jane Sheehan		1 Tube x 14g Cream	203 QTY	7.5mg Kit	102	QTY		Discretionary Quantity		Mytrin	400 QTY	New Patient Start Quantity		Ac21 Tube	401 QTY	Notes:			
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TAP PHARMACEUTICALS INC. - EPSILON COPY																																									

On August 24, 1992 you call on Dr. Michael Jones (an OBG) and sampled two kits of Lupron 3.75mg, one for a new patient (Jane Sheehan) and one at your discretion. You also left one box of Ogen .625mg and detailed him on Lupron and Ogen.



**White Copy:** Send to Epsilon on a weekly basis, using the Epsilon Business Reply Mail Envelope supplied to you

**Green Copy:** Retain for your records. File by month for reconciliation purposes

**Pink Copy:** Leave with the physician for the physician's records

To avoid return:

- Date must be legible.
- Quantity must be legible:
- Physician's signature:
  - Must match preprinted name on the card
  - No rubber stamps
  - No white-out or corrections
  - Other staff can not sign for physician(e.g. nurse)

TAP 5109647

## Reporting Call/Sample Activity

### Recording Sample/Call Activity with Blank Cards

If you are going to sample/detail a physician and you do not have a card preprinted with the physician's name, you can use a blank card to report your activity. This section explains how to fill out and submit a blank card. It also shows how to avoid having the card returned to you.

All entries must be in ink (press firmly).

**NOTE:** The use of multiple ink colors within the physician signature box or multiple ink colors in the sample quantity box should be avoided as it may suggest tampering.

Step 1     ✓     Check the box:

☐ Record Sample/Call Activity Only

Step 2     ✎     Fill in the full physician name, address of where sample was left, designation (MD or DO) and Epsilon ID #(if you have it). To ease processing, find the Epsilon ID # on the Epsilon Master List.

Step 3     ✎     Fill in the date of the call. Cards without a date will be returned to you.

Step 4     ✓     If you detail the product, check the box:

☐ (✓ if detailed)

Step 5     ✎     Fill in the quantity of kits or boxes of each drug sample you leave with the physician. Place the number on the far right side of the card before the word "QTY".

Step 6     ✎     Write how many of the Lupron Kits given as samples (3.75mg and 7.5mg separately) were for new patient starts and how many were given at your discretion. The total of these two numbers must equal the number shown at the right side of the card by the word "QTY".

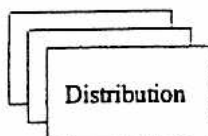
Step 7     ✎     In the Notes section, if Lupron samples were left for new patient starts, list the name of each patient involved

**NOTE:** White-out or corrections are not acceptable by law. If you make an error, use a new card.

Step 8     ✎     If you leave a sample, the physician must personally sign the card. The physician's signature must match the physician named on the card. Other staff can not sign for the physician. Rubber stamps are not acceptable. Unsigned cards will be returned to you.

<b>TAP PHARMACEUTICALS INC.</b> <b>Sample Signature Card</b> 1232840		EPSILON ID # 20145679A	DATE OF CALL (MM/DD/YY) 8/24/92
<input checked="" type="checkbox"/> RECORD SAMPLE/CALL ACTIVITY ONLY <input type="checkbox"/> ADD (PRE-PRINTED CARD REQUESTED) ENTER INFORMATION ON FRONT OF CARD		<input type="checkbox"/> CHANGE (ENTER CHANGES ON BACK OF CARD) <input type="checkbox"/> NO LONGER IN TERRITORY (MOVED OR DECEASED)	
Michael Jones 123 Circle Tree Place New Town, USA 12345		(MD) DO SPECIALTY: OBG	
TAP ACCT. #: 00011657 PHONE #: AXA42 TERM. #: 00016006		TAP ACCT. #: 00011657 CARRIER: 3 EMP. ACCT. #: 00016006	
I REQUEST AND ACKNOWLEDGE RECEIPT OF THE # ITEMS INDICATED HEREON FOR THE MEDICAL NEEDS OF MY PATIENTS. I CERTIFY THAT I AM CURRENTLY LICENSED WITH THE APPROPRIATE STATE AUTHORITIES TO RECEIVE THESE SAMPLES.			
X <u>Dr. Michael Jones</u> Physician Signature			
Lupron Depot # 100 3.75mg Kit 101 2 QTY <input checked="" type="checkbox"/> Discretionary Quantity <input checked="" type="checkbox"/> New Patient Start Quantity Name: <u>Jane Sheehan</u>		Epsilon Code Ogen # 200 <input checked="" type="checkbox"/> 625mg 625 mg Tab 201 1 QTY 1.25 mg Tab 202 QTY 1 Tube x 14g Cream 203 QTY Hytrin # 400 <input type="checkbox"/> 5 mg 5mg Tab 401 QTY	
TAP PHARMACEUTICALS INC. - EPSILON COPY			

On August 24, 1992 you call on Dr. Michael Jones (an OBG) and sample two kits of Lupron 3.75mg, one for new patient (Jane Sheehan) and one at your discretion. You also left one box of Ogen .625mg and detailed him on Lupron and Ogen. You have, however, run out of preprinted cards for Dr. Jones and need to use a blank card.



**White Copy:** Send to Epsilon on a weekly basis, using the Epsilon Business Reply Mail Envelope supplied to you

**Green Copy:** Retain for your records. File by month for reconciliation purposes

**Pink Copy:** Leave with the physician for the physician's records

**To avoid return:**

- Full physician name, including full first name and designation (MD or DO)
- Full address where samples were left
- Date must be legible.
- Quantity must be legible.
- Physician's signature:
  - Must match preprinted name on the card
  - No rubber stamps
  - No white-out or corrections
  - Other staff can not sign for physician(e.g. nurse)

TAP 5109649

## Reporting Call/Sample Activity

### Call Activity/Detail only with Pre-printed Cards

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If your call on a physician does not involve sampling, but you did detail a product (other than Lupron), you must still record the activity. This section explains how to fill out and submit a preprinted card to report call activity for a physician. It also shows how to avoid having the card returned to you.

---

All entries must be in ink (press firmly).

Step 1    ✓    Check the box:

☐ Record Sample/Call Activity Only

Step 2    ✎    Fill in the date of the call.

Step 3    ✓    Check the box of the product you detail:

☐ (✓ if detailed)

### Recording Call Activity/Detail Only with a Blank Card

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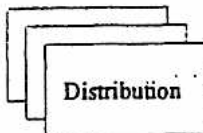
To record call activity with blank cards, follow the above steps and fill in the physician name, address, designation (MD or DO) and Epsilon ID #, if you have it. You can find the Epsilon ID # on the Epsilon Master List.

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TAP 5109650

<b>TAP PHARMACEUTICALS INC.</b> <b>Sample Signature Card</b>		EPSILON # 20146357A	DATE OF CALL (MM/DD/YY) 8/24/92
1232840			
<input checked="" type="checkbox"/> RECORD SAMPLE CALL ACTIVITY ONLY <input type="checkbox"/> ADD (PMS-PRINTED CARD REQUESTED) ENTER INFORMATION ON FRONT OF CARD		<input type="checkbox"/> CHANGE (ENTER CHANGES ON BACK OF CARD) <input type="checkbox"/> NO LONGER IN TERRITORY (MOVED OR DECEASED)	
Michael Jackson, MD 438 Fruit Street Fruitvale, CA 96487		MD 00 FORMER NAME	
SPECIALTY: URO			
ME # 901-765-3645 PHONE # 901-765-3645 TERM # AXAA2		TAP ADCT. # 01208745 # CAPSULES: 3 EMPL ADCT. # 00016006	
I REQUEST AND ACKNOWLEDGE RECEIPT OF THE RX ITEMS INDICATED HEREON FOR THE MEDICAL NEEDS OF MY PATIENTS. I CERTIFY THAT I AM CURRENTLY LICENSED WITH THE APPROPRIATE STATE AUTHORITIES TO RECEIVE THESE SAMPLES.			
X _____ Physician Signature			
Lupron Depot # 100 3.75mg Kit 101 QTY _____ _____ Discretionary Quantity _____ New Patient Start Quantity Notes: _____		Ogan # 200 <input type="checkbox"/> (if detailed) 328 625 Tabs 201 QTY _____ 1.25 625 Tabs 202 QTY _____ 1 Tube 8 14g Cream 203 QTY _____ Hytrin # 400 <input checked="" type="checkbox"/> (if detailed) 621 Tabs 401 QTY _____	
TAP PHARMACEUTICALS INC. - EPSILON COPY			

On August 24, 1992 you call on Dr. Jackson (a URO) and detailed him on Lupron and Hytrin. No samples are left.



Distribution

**White Copy:** Send to Epsilon on a weekly basis, using the Epsilon Business Reply Mail Envelope supplied to you

**Green Copy:** Retain for your records.

**Pink Copy:** Leave with the physician for the physician's records

To avoid return:

- Date must be legible.
- Check which product was detailed
- If you are using a blank card, full name, address and specialty must be filled in and legible

TAP 5109651

## Reporting Call/Sample Activity

### Adding a Physician Only

---

You have just found a physician who has opened a new office in your territory. The physician at this office is not shown on your Physician Master List. This section explains how to fill out and submit a blank card to add the doctor and the new address to that list. This will also provide you with preprinted cards for the Doctor in your next Rep Call Card Kit. This section also shows how to avoid having the card returned to you.

---

Step 1     ✓     Check the box:

☐ Add (Pre-Printed Card Requested)

Step 2     ✎     Fill in the date of add for physician.

Step 3     ✎     On the Front of the card:

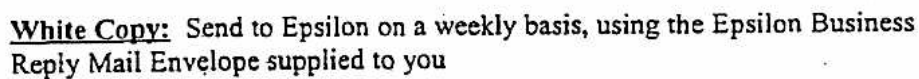
Fill in the physician full name, designation (MD or DO) and complete address. Enter the physician's ME # and TAP Customer #, if available.

Step 4     ✎     On the Front of the card:

Specify the # of cards/kits that you want to receive for this physician.

TAP 5109652

*On August 20, 1992 you find out Dr. John Smith, a URO, has just opened an office in your territory and it is not shown on your Physician Master List. You want to add him to your list.*



**Pink Copy:** Discard

- Full name, medical designation (MD or DO), address and specialty must be filled in and legible
- Date must be legible..

Page 2-9

## Reporting Call/Sample Activity

### Adding a Physician and Sampling

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You have just found a physician who has opened a new office in your territory. This physician at this office is not shown on your Physician Master List. You are going to visit him/her and you want to leave samples. This section explains how to fill out and submit a blank card to add the doctor to that list and record all your activities. This will also provide you with preprinted cards for them with your next Rep Call Card Kit. This section also shows how to avoid having the card returned to you.

---

Step 1     ✓     Check the boxes:

☐ Add (Pre-Printed Card Requested)

☐ Record Sample/Call Activity Only

Step 2     ✎     Fill in the date of call as the date of add for this physician.

Step 3     ✎     Fill in the full physician name, designation (MD or DO) and complete address. Enter the physician's ME # and TAP Customer #, if available.

Step 4     ✎     Specify the # of cards/kit that you want to receive for this physician.

Step 5     ✓     If you detail the product, check the box:

☐ (✓ if detailed)

Step 6     ✎     Fill in the quantity of kits or boxes of each drug sample you leave with the physician. Place the number on the far right side of the card before the word "QTY".

Write how many of the Lupron Kits given as samples (3.75mg and 7.5mg separately) were for new patient starts and how many were given at your discretion. The total of these two numbers must equal the number shown at the right side of the card by the word "QTY".

In the Notes section, if Lupron samples were left for new patient starts, list the name of each patient involved.

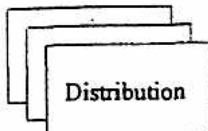
**NOTE:** White-out or corrections are not acceptable by law. If you make an error, use a new card.

Step 7     ✎     If you leave a sample, the physician must personally sign the card. The physician's signature must match the physician named on the card. Other staff can not sign for the physician. Rubber stamps are not acceptable. Unsigned cards will be returned to you.



<b>TAP PHARMACEUTICALS INC.</b> <b>Sample Signature Card</b> 1232840		Epsilon ID # _____ DATE OF CALL (MM/DD/YY) <b>8/20/92</b>	
<input checked="" type="checkbox"/> RECORD SAMPLE CALL ACTIVITY ONLY <input checked="" type="checkbox"/> ADD (NO S-PRINTED CARD REQUESTED) ENTER INFORMATION ON FRONT OF CARD		<input type="checkbox"/> CHANGE (ENTER CHANGES ON BACK OF CARD) <input type="checkbox"/> NO LONGER IN TERRITORY (MOVED OR DECEASED)	
John Smith 457 East Street Newtown, USA 12345 SPECIALTY: URO ME # _____ TAP ACCT. # _____ PHONE # 312-462-9715 # CANDIDATE: 3 TERR. # AXA42 EMP. ACCT. # 00016006		Lupron Depot # 100 3.75mg Kit 101 QTY _____ Discontinuation Quantity _____ New Patient Start Quantity _____ Name: _____ 7.5mg Kit 102 2 QTY _____ Discontinuation Quantity _____ New Patient Start Quantity _____ Name: John Jackson Bob Samson	
I REQUEST AND ACKNOWLEDGE RECEIPT OF THE #s ITEMS INDICATED HEREON FOR THE MEDICAL NEEDS OF MY PATIENTS. I CERTIFY THAT I AM CURRENTLY LICENSED WITH THE APPROPRIATE STATE AUTHORITIES TO RECEIVE THESE SAMPLES. X <u>John Smith</u> Physician Signature		Ogan # 200 <input type="checkbox"/> (1/8 oz each) 225 mg Tabs 201 QTY _____ 1.25 mg Tabs 202 QTY _____ 1 Tube 2 1/4 G Cream 203 QTY _____ Hytrin # 600 <input type="checkbox"/> (1/8 oz each) 401 QTY _____ <b>TAP PHARMACEUTICALS INC. - EPSILON COPY</b>	

On August 20, 1992 you find out Dr. John Smith, an URO, has just opened an office in your territory and is not shown on your Physician Master List. Doctor Smith already has an office in your territory at a different address. You visit the new office and sample 2 Lupron 7.5mg Kits for new patients (John Jackson and Bob Samson)



**White Copy:** Send to Epsilon on a weekly basis, using the Epsilon Business Reply Mail Envelope supplied to you

**Green Copy:** Retain for your records. File by month for reconciliation purposes

**Pink Copy:** Leave with the physician for the physician's records

To avoid return:

- Full physician name, including full first name and designation (MD or DO)
- Full physician address where samples were left
- Date must be legible.
- Quantity must be legible.
- Physician's signature:
  - Must match preprinted name on the card
  - No rubber stamps
  - No white-out or corrections
  - Other staff can not sign for physician (e.g. nurse)

TAP 5109655

## Reporting Call/Sample Activity

### Changing Physician Information Only

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You have found a physician on your Master List but the address for that physician is either wrong or has changed. This section explains how to fill out and submit a preprinted card to change the appropriate information. It also shows how to avoid having the card returned to you.

---

Step 1     ✓     **Front:**  
Check the box:

☐ Change

Step 2     ✎     Fill in the date of change for this physician

NOTE: Only changes on the BACK of the card will be entered.

Step 3     ✎     **Back:**  
On the back of the Sample Signature Card, fill in ONLY the physician information you want to change.

If you want to change the number of cards/kits that you receive for this physician, specify the new number of cards/kit on the back of the card.

NOTE: Do not use this card to record sample activity. Destroy any cards you have that show the wrong address and use blank cards to record any future activity (see page 2-4) until new preprinted cards are sent to you with your next Rep Kit.

### Indicating a Physician is No Longer in Territory

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To indicate that a physician is no longer in your territory, simply check that box on the front of the Sample Signature Card. Verify that the physician's name and address information is correct so the proper physician is removed. You will no longer receive preprinted cards for this physician.

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TAP 5109656

<b>TAP PHARMACEUTICALS INC.</b> <b>Sample Signature Card</b> <b>1232840</b>		EPSILON ID #    20145679A	DATE OF CALL (MM/DD/YY)    5/10/92																																				
<input type="checkbox"/> RECORD SAMPLE CALL ACTIVITY ONLY <input checked="" type="checkbox"/> CHANGE (ENTER CHANGES ON BACK OF CARD) <input type="checkbox"/> ADD 1 PRE-PRINTED CARD REQUESTED (ENTER INFORMATION ON FRONT OF CARD) <input type="checkbox"/> NO LONGER IN TERRITORY (MOVED OR DECEASED)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2">Epsilon Code</th> <th colspan="2">Epsilon Code</th> </tr> <tr> <td>Lupron Depot • 100</td> <td></td> <td>Ogan • 200</td> <td><input type="checkbox"/> (if 2 distinct)</td> </tr> <tr> <td>3.75mg Kit    101</td> <td>QTY</td> <td>A28 6x25 Tabs    201</td> <td>QTY</td> </tr> <tr> <td colspan="2">Discontinuation Quantity</td> <td colspan="2">1.25 6x25 Tabs    202</td> </tr> <tr> <td colspan="2">New Patient Start Quantity</td> <td colspan="2">1 Tube &amp; bag Cream    203</td> </tr> <tr> <td colspan="2">Notes:</td> <td colspan="2">Hytrin • 400</td> </tr> <tr> <td colspan="2"></td> <td colspan="2"><input type="checkbox"/> (if 2 distinct)</td> </tr> <tr> <td colspan="2"></td> <td colspan="2">B21 Tabs    401</td> </tr> <tr> <td colspan="2"></td> <td colspan="2">QTY</td> </tr> </table>		Epsilon Code		Epsilon Code		Lupron Depot • 100		Ogan • 200	<input type="checkbox"/> (if 2 distinct)	3.75mg Kit    101	QTY	A28 6x25 Tabs    201	QTY	Discontinuation Quantity		1.25 6x25 Tabs    202		New Patient Start Quantity		1 Tube & bag Cream    203		Notes:		Hytrin • 400				<input type="checkbox"/> (if 2 distinct)				B21 Tabs    401				QTY	
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Notes:		Hytrin • 400																																					
		<input type="checkbox"/> (if 2 distinct)																																					
		B21 Tabs    401																																					
		QTY																																					
Gail Johnson, MD 345 95th Street Hometown, SA 45678  SPECIALTY: URO ME # _____ TAP ACCT # 01086735 PHONE # 312/678/9101    # CARDS/KIT: 3 TERR # AXA42    EMPL ACCT # 00016006		<div style="border: 1px solid black; padding: 5px; margin-top: 10px;">         I REQUEST AND ACKNOWLEDGE RECEIPT OF THE ITEMS INDICATED HEREON FOR THE MEDICAL NEEDS OF MY PATIENTS. I CERTIFY THAT I AM CURRENTLY LICENSED WITH THE APPROPRIATE STATE AUTHORITIES TO RECEIVE THESE SAMPLES.          X _____          Physician Signature       </div>																																					
<b>TAP PHARMACEUTICALS INC. - EPSILON COPY</b>																																							

EPSILON ID # (If not listed on front)  
 Enter **ONLY** information which has changed below.

Name \_\_\_\_\_ (circle one)    MD    DO

Address 123 Circle Tree Court

City \_\_\_\_\_

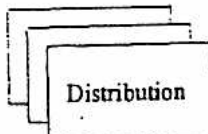
State \_\_\_\_\_ Zip \_\_\_\_\_ Phone \_\_\_\_\_

TAP Account # \_\_\_\_\_

Physician Specialty (circle one)    URO    ONC    OBG    FP    GP    IM    OTH \_\_\_\_\_

# Cards/Kit (circle one)    1    2    3    4    5    6    7    8    9

On May 10, 1992, you submitted an address change for Dr. Gail Johnson, a URO (Urology).



Distribution

**White Copy:** Send to Epsilon on a weekly basis, using the Epsilon Business Reply Mail Envelope supplied to you

**Green Copy:** Retain for your records. File by month for reconciliation purposes

**Pink Copy:** Leave with the physician for the physician's records

To avoid return:

- Date must be legible
- Changed information must be legible

TAP 5109657

## Procedures for Ordering Samples

---

This section contains the following:

Ordering Samples 3-2

Return of Sample Goods 3-4

---



## Procedures for Ordering Samples

### Ordering Samples


---

You only have enough samples for your activities for the next week and need to order more. This section explains how to order samples and what to do after the samples arrive.

---

- Step 1  To order product samples call TAP Customer Service at 1-800-621-1020 and ask for the Sample Coordinator. Have the following information available:
- Your personal account number \_\_\_\_\_  
(appears as Employee Account # on all your sample signature cards)
  - The product and quantity you want to order
  - The product you want to order and its list number (appears as the 9 digit product code to the left of the Epsilon code on all your sample signature cards)
- Step 2  Coordinate your activities so that someone is at your home to sign for samples being delivered.

NOTE: No sample orders will be shipped the last 5 days of the month.

- Step 3  Once shipment is received, verify the quantity received against the quantity on the packing slip.

TAP 5109659

## Procedures for Ordering Samples

### Return of Sample Goods

---

This section explains how to return samples you no longer need. The following is a list of reasons for returning samples. Returns for any other reason should be discussed with the manager of TAP Sales Administration.

- Damaged product
  - Expired product
  - Promotion to a position that does not require sampling
  - Leaving TAP
  - Relocating - Call your manager of TAP Sales Administration to find out if your relocation requires return of samples
- 

Follows these procedures for returning sample goods:

- Step 1     ☎     Call TAP Customer Service at 1-800-621-1020, and ask for the Sample Coordinator and have the following information from the packing slip:
- Date when samples originally shipped
  - Invoice number
  - Lot number
  - Your account number
  - Quantity to be returned
- Step 2     ✓     The Sample Coordinator will give you precise information on how to return products.

**NOTE:**     **DO NOT RETURN ANY SAMPLE WITHOUT FIRST TALKING WITH THE TAP SAMPLE COORDINATOR.**

WHOLESALE <b>Bob Berman</b>		SHIP TO CUSTOMER <b>0.00116006</b>		No. 007048																																																																														
STREET				<small>THIS FORM NOT TO BE USED FOR RETURN OF DEFECTIVE PRODUCT CONTACT YOUR TAP REPRESENTATIVE</small>																																																																														
CITY <b>Deerfield</b> STATE <b>IL</b>		ZIP <b>60015</b>		<small>IMPORTANT INSTRUCTIONS Please complete all required information. Write only. Do not stamp or sign. Return the top copy for your records. Place the remaining copy in the original container. This form is not valid unless it is signed by a TAP representative.</small>																																																																														
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AUTHORIZED BY <b>L. Hernandez</b>		TERMS <b>4838</b> DATE <b>12/1</b>		CORRECTIONS <b>B. Berman</b> INQ. # <b>T140769</b>																																																																														
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<small>1. PHARMACEUTICAL ITEMS MORE THAN ONE YEAR PAST EXPIRATION 2. PHARMACEUTICAL ITEMS NOT RETURNED IN FULL, UNOPENED, UNDAMAGED ORIGINAL UNIT OF SALE CONTAINER</small>																																																																																		
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>QTY.</th> <th>LIST TUC</th> <th>SALES SIZE</th> <th>DESCRIPTION</th> <th>STRENGTH</th> <th>PURCHASE DATE</th> <th>EXP. DATE</th> </tr> </thead> <tbody> <tr> <td>9</td> <td>36220</td> <td>045</td> <td>Lupron</td> <td>7.5</td> <td></td> <td></td> </tr> <tr> <td>12</td> <td>39430</td> <td>045</td> <td>Ogen</td> <td>625</td> <td></td> <td></td> </tr> <tr> <td>3</td> <td>24170</td> <td>045</td> <td>Ogen</td> <td>MUM</td> <td></td> <td></td> </tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>						QTY.	LIST TUC	SALES SIZE	DESCRIPTION	STRENGTH	PURCHASE DATE	EXP. DATE	9	36220	045	Lupron	7.5			12	39430	045	Ogen	625			3	24170	045	Ogen	MUM																																																			
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PRODUCTS RETURNED ARE SUBJECT TO TAP VALUATION AT TIME OF RECEIPT. TAP RESERVES THE RIGHT TO DESTROY RETURNED PRODUCTS WHICH WE FEEL ARE UNFIT OR UNSAFE FOR USE.																																																																																		
<small>REASON FOR RETURN</small> ENTER APPROPRIATE NUMBER 1) RECEIVED BROKEN      2) SHIPPING ERROR 3) OUT DATED PRODUCT      4) OVERSTOCKED 5) DUPLICATE SHIPMENT <small>**INCLUDE ORDER NUMBER AND DATE</small>			MANIFEST OF RETURNED GOODS PAGE <u>1</u> OF <u>1</u> <b>TAP Pharmaceuticals</b> CUSTOMER'S COPY																																																																															
<i>up promoted</i>																																																																																		

Returned Goods Authorization Form

Step 3 ✓ You will receive a Return Goods Authorization (RGA) form and mailing label from the TAP Samples Coordinator.

Step 4 Use the mailing label to ship product samples and be sure to enclose a copy of the RGA form.

**NOTE:** Avoid returning sample goods near the end of the month, as this may adversely affect your reconciliation process.

TAP 5109661

## Recording Inventory Movement

---

In order to record inventory movement of samples correctly you need to review the following:

Recording Monthly Physical Inventory	4-2
Verifying Inventory Figures with Your District Manager	4-2
Reviewing the Sampling Inventory Reconciliation Report	4-4
Reviewing the Sampling Inventory Detail Report	4-6
Submitting an Inventory Adjustment	4-8

---

TAP 5109662



## Recording Inventory Movement

### Recording Monthly Physical Inventory

---

**EVERY MONTH** you **MUST** report the number of samples you have in your possession. Your month end inventory will be compared to the results of all deliveries made to you, less samples you have distributed per the samples received by Epsilon. This section will describe how to fill out the form and how to avoid having the form returned to you.

---

**NOTE:** The physical inventory **MUST** be taken after the last sampling day of the month and before the first sampling day of the new month.

This inventory must be counted and recorded accurately as any error in counting will result in a variance on your report.

- Step 1     ✓     Verify that the month ending, which is preprinted on the Monthly Physical Inventory form, is the proper month ending for this physical inventory.
- Step 2     ✎     Fill in the quantity of each drug sample that you have in your possession. Enter the quantity in number of boxes. For example, Ogen .625 6 x 25 Tabs equals 1 box.
- Step 3     ✎     Sign and date the Monthly Physical Inventory form.

### Verifying Inventory Figures with Your District Manager

---

Approximately every six months your district manager will physically verify your inventory figures. If you are submitting a Monthly Physical Inventory that your district manager verified, have him/her sign and date the Monthly Physical Inventory form.

---

TAP 5109663

<b>MONTHLY PHYSICAL INVENTORY</b>		
DATE OF INVENTORY	12/92	
LOCATION	AXA42	
PHYSICIAN NAME	BOB BERMAN	
DATE, LAST INVENTORY	0016006	
PHYSICIAN ID NUMBER	204876	

SAMPLE	EPSILON CODE	QUANTITY ON HAND
Lupron Depot®	100	
3.75mg Kit	101	<u>5</u>
7.5mg Kit	102	<u>2</u>
Ogen®	200	
.625 8x25 Tab	201	<u>10</u>
1.25 8x25 Tab	202	<u>15</u>
1 Tube x 14g Cream	203	<u>3</u>
Hytrin®	400	
5x21 Tab	401	

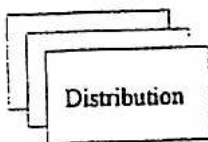
Representative Signature: Bob Berman Date: 12/30/92

I certify that the above physical inventory figures are correct.

DM Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**TAP PHARMACEUTICALS INC. - EPSILON COPY**

Monthly Physical Inventory Form December, 1992



**White Copy:** Send to Epsilon® on a weekly basis, using the Epsilon Business Reply Mail Envelope supplied to you

**Green Copy:** Retain for your records. File by month for reconciliation purposes

**Pink Copy:** Leave with the physician for the physician's records

To avoid return:

- Proper Month/Year
- Legible quantities
- Representative's signature
- District Manager's signature, if applicable.

TAP 5109664

## Recording Inventory Movement

A variance between the number of product samples calculated to be on hand and actually in your possession can occur for a number of reasons. You will receive two reports from Epsilon each month to help you reconcile any such variances: a **summary report** and a **detail report**.

You will continue to receive inventory reports for the months that are out of balance until your inventory is put back in balance and the product variance is zero.

## Reviewing the Sampling Inventory Reconciliation Report

---

Each month you will receive a copy of the Sampling Inventory Reconciliation Report. This report will show you the number of samples Epsilon believes you have. This is based on deliveries to you and the sample cards you submit to Epsilon. It will also show the inventory you reported in your possession (see page 4-2) and highlight all differences.

Using the Inventory Detail report (page 4-6,7) and your copies of the Sample Cards and Delivery Packing Slips, you are responsible to reconcile **ALL** differences shown. **The reason for each difference must be determined.** To learn how to reconcile these variances, view your "Samples are Simple" video.

---

The following are descriptions of the columns (from left to right) on the Sampling Inventory Reconciliation Report:

<b>This Month Beginning Balance</b>	The system calculates this number as the System Calculated Ending Balance from the previous month + late activity or adjustments for the previous month.
<b>Total Units Delivered</b>	The total number of units shipped to you during the month.
<b>Adjustments</b>	The total number of units adjusted through the TAP Sample Coordinator or on the Epsilon Inventory Adjustment form during the month.

TAP 5109665

TAP Pharmaceuticals Sampling Inventory Reconciliation Report For Period 05/01/92 - 05/31/92							
Territory: AXA65 Employee: 00012345 Jones, Robert		As Of: 6/20/92					
Product/Sample	This Month Beginning Balance	Total Units Delivered	Adjustments	Total Units Hand Sampled	System Calculated Ending Balance	Rep Physical Inventory Ending Balance	Variance
Lupron 3.75mg Kit	5	3	0	2	8	8	0
Lupron 7.5mg Kit	4	12	1	2	15	14	-1
Ogen .625 6x25 Tabs	10	12	0	20	2	2	0
Ogen 1.25 6x25 Tabs	6	0	0	5	1	1	0
Ogen 1 Tube x 14g Cream	7	0	0	5	2	2	0

*Sampling Inventory Reconciliation Report for May, 1992.*

**Total Units Sample** The total number of units you recorded as sampled on the Signature Cards for the month, that were processed by Epsilon.

**System Calculated Ending Balance** The system calculates this number as follows:

	This Month Beginning Balance
+	Total Units Delivered
±	Adjustments
-	Total Units Hand Sampled
=	System Calculated Ending Balance

**Rep Physical Inventory Ending Balance** The quantity on hand that you submitted on your Monthly Physical Inventory form for the same month.

**Variance** The system calculates the variance as the difference between the System Calculated Ending Balance and the Rep Physical Inventory Ending Balance.

TAP 5109666

## Recording Inventory Movement

### Reviewing the Sampling Inventory Detail Report

---

Each month you will receive a copy of the Inventory Detail Report. This report will list all the sample cards processed by Epsilon. It is used with the Sampling Inventory Reconciliation Report and your green copy of the sample cards, to reconcile all variances between Epsilon's calculated month end Inventory and the amount you reported. To learn how to reconcile these variances, view your "Samples are Simple" video.

---

- Step 1     ✓     Compare your green copies of the sampling signature cards, adjustments, sample packing slips and returns with the items on the Inventory Detail Report.
- Step 2     ✓     If you find any activities missing, follow these steps:
- Double check that you did send the item to Epsilon and sufficient mailing time has passed.
  - Call Epsilon Customer Service at 1-800-231-7711 to determine if the missing document was received.
    - If Epsilon has the document, you do not need to do anything further. The system will take care of the missing activity next month.
    - If Epsilon does not have the document and sufficient mailing has passed, go to Step 3.
- Step 3     ✓     If the document has been lost in the mail, follow these steps:
- Attach a photocopy of your green copy to an adjustment form and treat this activity as a newly submitted adjustment (see Submitting an Inventory Adjustment on page 4-8.)
  - When Epsilon receives this adjustment, Epsilon will check to make sure the document is not already in the system. If it is in the system, Epsilon will send the document back to you marked "Already Received."

TAP 5109667

TAP Pharmaceuticals Sampling Inventory Reconciliation Report For Period 05/01/92 - 05/31/92						
Territory: AXA55 Employee: 00012345 Jones, Robert			As Of: 6/20/92			
Transaction Type	Physicians Name	Product Code	Serial #	Territory	Activity Date	Quantity
Lupron 7.5mg Kits						
HAND SAMPLES	PAUL WEINSTEIN	03639-00-45	23526123	AXA55	5/10/92	1
HAND SAMPLES	TOM JONES	03639-00-45	23526158	AXA55	5/13/92	1
HAND SAMPLES	JAMES KEATON	03639-00-45	23516248	AXA55	5/17/92	3
HAND SAMPLES	PAUL WEINSTEIN	03639-00-45	23516355	AXA55	5/18/92	2
HAND SAMPLES	GEORGE SMITH	03639-00-45	23526532	AXA55	5/20/92	1
						8
DELIVERY		03639-00-45		AXA55	5/10/92	12
						12

*Sampling Inventory Detail Report for May, 1992.*

Step 4 ✓ If you do not find any sampling activities missing on the Detail Report, one of the three reasons below may apply:

- Theft

If you were a victim of a robbery which involved samples, you must notify the police and attach a police report to an adjustment form.

- Shipping

Check your packing slips and Returned Goods Authorization (RGA) forms against the Detail Report. If sufficient mailing time has passed and a RGA does not show up on the report, then call the TAP Sample Coordinator at 1-800-621-1020.

- Undermined

The cause of the variance cannot be determined. Fill out an adjustment form, include an explanation and send it to Epsilon.

TAP 5109668






## Recording Inventory Movement

### Submitting an Inventory Adjustment

---

After you have reconciled ALL the variances on the Sampling inventory Reconciliation Report, you may be required to make an adjustment to the system. This section explains how to find out and submit an Adjustment Form. It also shows how to avoid having the form returned to you.

---

- Step 1     Fill in the date you are making the adjustment (today's date).
- Step 2     Fill in the month/year of the inventory you are adjusting.
- Step 3     Fill in the quantity of the adjustment by product in the proper column.
- Step 4     Attach written explanations or documents as necessary.
- Step 5     Sign and date the Inventory Adjustment form.
- Step 6        Mail document to Epsilon using an Epsilon Business Reply Envelope,

TAP 5109669

**TAP PHARMACEUTICALS INC.**  
**Epsilon Inventory Adjustment** 7009927

TERMINAL: AXA42 Epsilon NUMBER: 2537485P  
 EMPLOYEE NAME: Connor, C. ENPL ADJUST NUMBER: 00016006  
 Date of Adjustment (Today's Date - MM/DD/YY) 6/3/92 Month/Year of Inventory (To Be Adjusted) 4/92

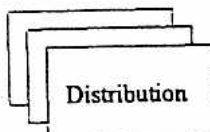
Sample	Epsilon Code	Quantity			Explanation (REQUIRED - Please attach additional forms if necessary)
		Thick (Green/Pink) Primary	Loss (Phone) Expiry	Add (Phone) Expiry	
Lupron Depot <sup>®</sup>	100	(-)	(-)	(+)	
3.75mg Kit	101				
7.5mg Kit	102				
Open <sup>®</sup>	200	(-)	(-)	(+)	
825 Br25 Tabs	201				
1.25 Br25 Tabs	202				
1 Tube x 14g Cream	203		1		card never rec'd by Epsilon <sup>SEP</sup> Attachment
Hytrin <sup>®</sup>	400	(-)	(-)	(+)	
5x21 Tabs	401				

**TAP PHARMACEUTICALS INC.**  
**EPSILON COPY**

*Charles Connor*  
 Representative Signature:

6/3/92  
 Date:

On June 3, 1992, Charles Connor made an adjustment for 1 Tube of 14g Cream due to a lost call card. The April 1992 inventory is adjusted for that amount and the lost call card is being attached.



**White Copy:** Send to Epsilon on a weekly basis, using the Epsilon Business Reply Mail Envelope supplied to you

**Green Copy:** Retain for your records. File by month for reconciliation purposes

- To avoid return:**
- Month/year of the Inventory being adjusted
  - Signature, date and legible explanation for each adjustment
  - Copies of supporting documentation when necessary

TAP 5109670



### Prescription Drug Marketing Act of 1987

The following statements are removed from the Prescription Drug Marketing Act of 1987 which is legislation that pharmaceutical companies must follow in regards to sample programs.

Sec. 4(c)(1) "No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d), the term 'drug sample' means a unit of the drug, subject to subsection (b), which is not intended to be sold and is intended to promote the sale of the drug."

Sec. 5(2)(A) "The manufacturer or distributor of a drug subject to subsection (b) may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals, or other health care entities. Such a distribution of drug samples may only be made -

"(i) in response to a written request for drug samples made on a form which meets the requirements of subparagraph (B), and

"(ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or distributor.

Sec. 5(2)(B) "A written request for a drug sample required by subparagraph (A)(i) shall contain -

"(i) the name, address, professional designation, and signature of the practitioner making the request,

"(ii) the identity of the drug sample requested and the quantity requested,

"(iii) the name of the manufacturer of the sample requested, and

"(IV) the date of the request.

Sec. 5(2)(C) "Each drug manufacturer or distributor which makes distributions by mail or common carrier under this paragraph shall maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and shall maintain a record of distributions of drug samples which identifies the drugs distributed and the receipts of the distributions. Forms, receipts, and records required to be maintained under this subparagraph shall be made available from the drug manufacturer or distributor to Federal and State officials engaged in the regulations of drugs and in the enforcement of laws applicable to drugs."

+